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Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,001,858 ('858) was filed on February 16, 2007, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Advantage® Multi, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our preliminary analysis of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156 unless the Food and Drug Administration considers the combination of imidacloprid and moxidectin to be a single entity. According to the statute:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if —
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> . . .
>
> (5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;
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> . . . .
>
> (f) For purposes of this section:
>
> (1) The term "product" means:
>
> (A) A drug product.
>
> . . .
>
> (2) The term "drug product" means the active ingredient of—
>
> (A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)

. . .

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

35 U.S.C. § 156.

Applicant admits at pages 2-3 of the PTE Application that both active ingredients of Advantage® Multi have been previously approved. Imidacloprid had been subject to a regulatory review period under § 512 of the Federal Food Drug and Cosmetic Act (FFDCA) and approved for commercial marketing or use in the product Advantage® DUO (where imidacloprid was approved for use in combination with ivermectin) on September 27, 2002. The other active ingredient, moxidectin, had been subject to regulatory review period under § 512 of the FFDCA, alone in NADA Nos. 141-051, 141-087, 141–099, 141-189141-220 and 141-247 and with praxziquantel in NADA No. 141-216, where each listed NADA had been approved prior to the approval of Advantage® Multi.

The term "product" as used in 35 U.S.C. § 156 includes any new drug or antibiotic drug, as a single entity or in combination with another active ingredient. See 35 U.S.C. § 156(f). "For a product which contains a plurality of active ingredients . . . the statute must be analyzed with respect to each active ingredient." See "Request for Patent Term Extension Final Decision," dated March 3, 1994, in U.S. Patent No. 4,529,601 (copy attached). If a drug product contains two active ingredients and both of the active ingredients have been previously approved, then regulatory review of the combination product cannot be relied upon for extension of a patent claiming the approved drug product. See In re Alcon Laboratories, 13 USPQ2d 1115 (Comm'r 1989). Since imidacloprid and moxidectin have been previously approved individually, their use in a combination product does not appear to comply with 35 U.S.C. § 156(a)(5)(A), *i.e.*, the approval of Advantage® Multi would not appear to constitute the first permitted commercial marketing or use of the product as required by 35 U.S.C. § 156(a)(5)(A). Because the combination product does not appear to comply with 35 U.S.C. § 156 (a)(5)(A), U.S. Patent No. 6,001,858 does not appear to be eligible for patent term extension based upon the regulatory review period of Advantage® Multi. See also Fisons plc v Quigg, 8 USPQ2d 1491 (D.D.C. 1988).

It is the position of the USPTO that a product which is nothing more than a combination of previously approved active ingredients fails to satisfy 35 U.S.C. § 156(a)(5)(A). This position is supported by the decision of the Federal Circuit in Arnold Partnership v Dudas, 70 USPQ2d 1311 (Fed. Cir. 2004), where the court addressed whether a patent directed to a combination of active ingredients would qualify for a patent term extension under § 156. The court stated, "[t]his statutory language [referring to subsection 156(f)] requires this court to examine a drug product patent's eligibility for extension on a component-by-component basis." Id. at 1314. The court's analysis focused on the statutory language relating to "drug product." Specifically, the court reasoned that the statutory language:

> . . . places a drug product with two active ingredients, A and B, in the same category as a drug product with a single active ingredient. In both instances, those active ingredients individually qualify for examination under the first permitted marketing requirement. To extend the term of a patent claiming a composition comprising A and B, either A or B must not have been previously marketed. In other words, at least one of the claimed active ingredients must be new to the marketplace as a drug product.

Id. at 1314.

In looking at the combination drug product at issue in Arnold Partnership, the court concluded that since both ibuprofen and hydrocodone bitartrate had each been previously approved individually, extension of U.S. Patent No. 4,587,252 was not permitted because of the failure to comply with 35 U.S.C. § 156(a)(5)(A). Applying this rationale here, the previous approvals of imidacloprid and moxidectin, alone and in combination with other active ingredients, bar the '858 patent from extension under 35 U.S.C. 156 because of failure to comply with 35 U.S.C. § 156(a)(5)(A). Thus, it is clear that a combination of previously approved active ingredients does not constitute the first permitted commercial marketing or use of the product which was subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g).

Therefore, the approval for Advantage® Multi referenced in the application for patent term extension does not appear to represent approval as "the first permitted commercial marketing or use of the product" as required by § 156(a)(5)(A), and, therefore, U.S. Patent No. 6,001,858 would appear to be **ineligible** for extension.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
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Office of the Deputy Commissioner
for Patent Examination Policy

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